Paper presented in the IV Globelics Conference at Mexico City, September 22-24 2008

Globelics

The patenting of genetic resources and the privatization of strategic public goods

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1. Introduction

Since the recognition of the sovereign rights of countries over their genetic resources by the Convention on Biological Diversity (CBD, 1993), developing countries rich in biodiversity have become more aware of the potential value of their resources. As a consequence their governments have engaged in the drafting and implementation of laws for controlling access to their genetic resources, which some consider as strategically important natural resources, on a par with oil and minerals (Ruiz-Caro, 2005)

Besides implementing tough regulations at the national level, their representatives have found that there is an essential clash between the aims of the CBD and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreements of the World Trade Organization (WTO). It has been argued that TRIPS promotes the illegal appropriation of biological, genetic resources and traditional knowledge of communities via the patenting system. In order to inhibit biopiracy, developing countries have asked for changes to the patenting system to include new requirements, such as proof of legal acquisition and disclosure of the country of origin of genetic material at the point of filing a patent.

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The disclosure of the origin of genetic resources has divided the representatives of developing countries from those of the developed world at both the Conference of the Parties and the TRIPS Council at the WTO. While the former argue that the disclosure of origin is a necessary element for the control of biopiracy the representatives of Australia, Canada, Japan, New Zealand and the United States (the latter not a party of the Convention but an observer), together with industry organizations, question the need of an international regime linked to the patenting system. They consider that imposing a system of regulation to verify the legal origin of a genetic resource would deter bioprospecting and investment in biotechnology, given that bioprospecting is not as lucrative as it has been assumed, and therefore would not justify the cost and inconvenience of compliance (ICTSD, 2004).

This paper presents a "reality check" for those engaged in policy formulation in access and benefit sharing (ABS). It identifies the firms and technologies involved in the use of genetic and biological resources; the size of the bioprospecting business and the difficulties of calculating the value of the genetic information and/or traditional knowledge associated with it. The paper also discusses the efficacy of the proposed regime in terms of guaranteeing the fairness of bioprospecting contracts and the availability of the resources for innovation purposes.[2] [3]

[2] It is worth noting that this research does not include the use of genetic resources in agriculture.
[3] Bioprospecting is the purposeful evaluation of wild biological material in search of valuable characteristics - seems to be a powerful way for firms to develop new pharmaceuticals, agrochemicals, cosmetics, flavourings, fragrances and industrial enzymes, among others (Artuso, 2002).

The paper also shows how assumptions of the CBD as the exchange of potentially valuable genetic and biological resources in a unidirectional process between source countries of the developing world and international firms (mainly in the pharmaceutical sector) of the developed world are misplaced. The paper concludes by showing that the business of biotechnology is far more complex than the regulatory framework now in place assumes and that the diverse nature, roles and purposes of the actors involved needs to be more fully understood.

2. The implementation of access and benefit sharing provisions: a path paved with obstacles

2.1 Access and benefit sharing to finance conservation

Biodiversity is a public good that provides global environmental services such as the control of temperature of the planet and the patterns of rainfall. In an attempt to face the challenges posed by the erosion of biodiversity, experts, citizens and representatives from all over the world met at the United Nations Environment Conference, also known as The Earth Summit, in Rio de Janeiro in 1992. The Conference culminated with the agreement of a fundamental instrument to promote the sustainable use of biodiversity, the Convention on Biological Diversity (hereafter, CBD or the Convention). The Convention constituted a change in the status of biological and genetic resources, previously considered the common heritage of humankind, giving national governments sovereign rights over them.

One of the most important issues emerging from the summit was the need to control the access to biological and genetic resources, mainly located in developing countries, at the same time as providing incentives and ensuring financing for conservation. The Convention proposes the establishment of partnerships between firms interested in exploiting the chemical diversity of nature (users) and national governments of biodiversity rich countries (providers). In principle both partners would benefit from such bioprospecting agreements: firms, by having access to important sources of compounds for future product development; and governments by receiving financial resources, technology and training to support conservation activities.

Bioprospecting partnerships were considered the best way for developing countries to finance conservation, acquire research capabilities and participate from the profits of firms in sectors depending on biological and genetic material (Reid, 1996). The contract between Merck and The National Institute on Biodiversity (INBio) of Costa Rica, by which the latter agreed to provide the firm with samples for an upfront payment of $1million, provided training for INBio's personnel and laboratory equipment. This soon became the model for negotiating bioprospecting agreements worldwide. Developing countries rich in biodiversity developed major expectations about the possibility of participating in the multimillion dollar profits of the pharmaceutical industry, at the same time as gaining scientific and technological capabilities to take advantage of their natural resources.

However, after the initial enthusiasm for agreements to explore biodiversity, bioprospecting came under attack; environmentalists and civil society organizations were among the first to claim that firms engaged in bioprospecting were plundering developing countries of their biodiversity richness and 'stealing' associated knowledge from indigenous peoples. It was claimed that intellectual property rights over biological material unleashed accusations of biopiracy and patents became the instrument used by firms to 'pillage' developing countries of their natural wealth (Shiva, 1996; ETC Group, 2004). The fact that the massive financial gains associated with biodiversity exploration were never generated seemed to confirm that multi national firms were acting to the detriment of the interests of developing countries.

2.2 The international regime on access and benefit sharing

Given the mistrust between the agents involved, and the suspicion under which bioprospecting activities were being carried out, the need for developing access and sharing of benefits (ABS) regulations became apparent. The adoption of the Bonn Guidelines at the VI Conference of the Parties of the Convention (2002) was considered an important step for establishing legislative, administrative or policy measures when negotiating contractual bioprospecting arrangements. The Guidelines recommended that users obtain the *previous informed consent* (PIC) of the national competent authority, as well as indigenous and local communities, as appropriate to the circumstances (Article 26d). Providers and users were due to share the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in *mutually agreed terms (*MAT, Article 42). The contracting parties were required to

establish arrangements about intellectual property, including the possibility of joint ownership according to the degree of contribution (Article 43).

Immediately after their adoption, the Bonn Guidelines became the object of criticism by environmentalists, who claimed they were insufficient to tackle issues of biopiracy, benefit sharing and protection of traditional knowledge (ETC, 2004). The voluntary nature of the Guidelines i.e. the fact that contracting parts are not obliged to comply with them, reinforced the allegation of environmental campaigners that powerless peoples and communities were being exploited. The Like-Minded Group of Mega-Diverse Countries (LMMCs), led by India, pushed for the establishment of an *international regime on ABS* to be implemented in order to facilitate the provisions of the CBD. [4]

The claims of developing countries also reached the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council at the Doha Round (Qatar, November 2001). In effect developing countries affirmed that there was a fundamental conflict between the CBD and TRIPS because, while the Convention ensures the sovereign rights of countries over their genetic resources, TRIPS promotes the illegal appropriation of biological, genetic resources and traditional knowledge of communities via the patenting system (Table 1). Again, the solution to such a conflict is the implementation of the international regime on access and benefit sharing that will link the protection of genetic resources and traditional knowledge to the patenting system.

[4] The group is formed by Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela, signatories of The Cancun Declaration (2002)

If the international regime was to be adopted, patent offices were be compelled to verify that the genetic resources involved in an invention were legally obtained with the previous informed consent of the community, as well as local and national governments. It also sought a benefit sharing agreement in mutually agreed terms between the firm applying for the patent and the provider of the resources, recognising the contribution of local communities. A series of instruments, such as an *International certificate of source,* to be given to the user by the provider (collection, firm, etc), or an *International certificate of legal provenance,* to be given by the provider to the user, to prove that the resources have been obtained from a legally entitled source have been proposed (Tobin, 2004).

The central piece of the international regime, strongly opposed by the representatives of some developed countries and multinational firms, is the requirement of the disclosure of origin of the resources. This is the obligation on patentees to disclose in the specification the origin of genetic resources and/or traditional knowledge relevant to the invention. So far three forms of implementation of such a requirement have been proposed (Dutfield, 2005):

- Voluntary, consisting in encouraging the disclosure of origin of the genetic resources and/or traditional knowledge relevant to an invention. In this form the omission of such information would not disqualify the patent application from being accepted, granted or subsequently enforced.

- Mandatory, with failure to disclose or dishonest disclosure having major consequences, such as the rejection of the patent application and the possibility of a patent being revoked, or not enforced, if granted.
- Proof of legal acquisition, requiring patent applicants to submit with their application official documentation from countries providing the genetic resources and/or traditional knowledge associated, including proof of PIC, MAT and benefit sharing agreements.

There is the possibility that, once provider countries have agreed on some common requirements and procedures, standardized certificates of origin could be used in all national and regional patent offices.

Table 1 Summary of Areas of Conflict between TRIPS and the CBD

Issue Area	TRIPS	CBD
Patentable subject matter	Circumscribes national sovereignty by mandating protection of biological and biotechnological innovations either through patents or sui generis protection	Principle of national sovereignty implies discretion in the drafting of IPR legislation, including the right to prohibit protection on biological resources
Benefit sharing	Strong private IPR with no corresponding rights for communities and farmers, and no mandated benefit sharing	Benefit sharing mandated, with the exact terms negotiated between government and interested parties
Protection of local knowledge	Narrow understanding of innovation associated only with commercial utility	Recognizes importance of indigenous knowledge
Role of the State	Role of the state to protect private intellectual property. No role in maintaining, promoting or protecting biodiversity	Access to biodiversity governed by principle of prior informed consent, including consultation with local communities

Source: Zerbe (2003), adapted from GRAIN (1998)

3. A look at the uses of genetic resources

After ten years of working in the field of regulating bioprospecting, ten Kate and Laird (2002) reached the conclusion that ABS provisions require a good understanding of recent developments in science, technology and industry in order to reach reasonable agreements. In effect, the unidirectional flow of genetic resources from provider countries to users at the bases of the Convention constitutes an oversimplification. The reality is that diverse firms utilize genetic resources from every possible region either in their original form, a modified form or simply as a source of information (e.g. genetic sequences), adding knowledge and carrying out investments in order to develop marketable products.

3.1 Firms in the pharmaceutical sector: the role of intermediaries

For decades natural products were the main source of compounds for the development of effective and successful medications. During the negotiations of the CBD the assumption that pharmaceutical firms would be prepared to pay in order to get access to the biodiversity richness of countries was considered the solution for financing environmental conservation activities. The possibility of getting a part of the annual sales of pharmaceutical products – estimated at around $ 200 billion – as well as getting access to new technologies, attracted the attention of provider countries, generating expectations about the implementation of the Convention.

Bioprospecting was an activity of particular interest for pharmaceutical firms, which sponsored expeditions to the more biodiverse countries in the world, after the discovery

of therapeutic molecules such as aspirin. After decades of collecting and analyzing samples, by the end of the 1970s the decline in the number of bioactive molecules being obtained from nature became apparent. By the early 1980s firms such as Brystol-Meyers Squibb decided to close down their natural product divisions while others, including Novartis, scaled down their efforts in the area since it was perceived that few novel active leads were being isolated from natural sources (Cordell, 2000; Gehl Sampath, 2005). Even the National Cancer Institute (NCI) program on natural products, with a history of more than forty years was discontinued and research directed to new areas (Cragg et al. 2000). Bioprospecting activities in the pharmaceutical industry had, by the late 1980s, been greatly reduced in scope and importance around the world.

Today, however, there is a renewed interest in going back to nature in search of new bioactive molecules. Technologies such as high-throughput screening (HTS) allow the fast and cheap analysis of a great number of molecules (Littleton et al. 2005). It is also expected that genomics, a relatively new technological area, will add thousands of receptors for therapeutic activity and will help in exploring the chemical diversity of nature. Surprisingly, when it seems the perfect moment for implementing the ABS provisions of the CBD has finally arrived, the world's biggest pharmaceutical firms declared either not using genetic resources for product development or not being aware of the consequences of the CBD over their work (Busch and Kern, 2005).

This, however, does not mean that firms are not interested in accessing the chemical diversity of nature anymore, but that they prefer not to carry out the collection of samples

themselves, using instead the vast network of providers of genetic resources that exist (academic and commercial). In effect, as a result of the accusations of biopiracy thrown to several bioprospecting projects involving – sometimes tangentially -pharmaceutical firms, they prefer not to engage directly in bioprospecting, preferring to access samples from intermediaries or outsourcing, such an activity to smaller firms with operations in developing countries. Among the intermediaries of genetic resources are commercial brokers, university researchers, firms dedicated to the preparation of extracts and firms that can add value to the rough genetic material by removing impurities and undesirable compounds, making it easier for pharmaceutical firms to screen molecules.

The work of academics in collecting samples from the biodiversity of different countries cannot be dismissed. Taxonomists and ethnobotanists, among other scientists dedicated to the study of biodiversity, have carried out bioprospecting for decades, frequently exchanging materials with colleagues of different countries. However it is necessary to remember that until recently such activities were considered "…*natural and justified, because the outcome benefits the scientific and general communities locally and globally…*" (Soejarto et al 2005). [5] We have found that collections created at universities are the foundation of some small firms providing samples to larger firms, or have been sold to firms specialized in creating molecular libraries.

[5] In the same way it is worth noting that the scientific community started discussing issues related to the access of biological and genetic resources, as well as traditional knowledge, long before the CBD went into force. In 1988 the International Society of Ethnobiology established what its members considered ethical terms to conduct research, taking into account the conservation of biodiversity and the respect of the peoples (ISE, 1988). After 1993 other professional groups such as the Society of Pharmacognosy, constituted by an important group of researchers from different countries dedicated to the development of biodiversity for medicinal purposes published the guidelines for its members, (Cragg et al, 1997)

However it is worth noting that the amount of money involved in genetic resources transactions are far from being considerable. Brokers of dried samples charge only between $3-5 per sample, while extracts can be bought for $10. The access to a molecular library of purified samples can be more expensive but is in no way prohibitive. In any case bioprospecting has been shown not to be a big business: INBio, the most prestigious institution when it comes to carrying out bioprospecting, received four upfront payments of around $6 million for providing samples to the pharmaceutical firm Merck in an eight year period.

The budget of the International Cooperative Biodiversity Groups (ICBG), through which the American government finance bioprospecting around the world, is also limited. The first set of awards, granted in 1993, reached an amount of $2.4 million to finance five projects for a five year period. With the entrance of new organizations funds available for the second set of awards reached $3.7 million. The third phase of the ICBG is currently sponsoring five projects in eight countries and seven plans for a total amount of $6 million. Recently INBio in Costa Rica was granted a full award of $3.5 million to carry out research with the University of Michigan. Although these are among the biggest bioprospecting projects, none approach the financial scale that would allow developing countries to reap significant benefits.

As pointed out by ten Kate and Laird (2002) the existence of intermediaries constitutes a major problem for the implementation of the provisions on ABS of the Convention. Some of them, such as botanical gardens and collections *ex situ*, frequently located in

developed countries have preferred an auto regulatory approach, restricting the use of the material provided to scientific research. Others, such as the Brazilian firm Extracta, have being authorized to collect samples of biodiversity and have to comply with the regulations of the country they operate in. The majority of intermediaries, however, have escaped regulation since their specialized activities are not obvious to the general public, or are carried in the framework of scientific agreements. Finally there are firms carrying out bioprospecting in territorial and international waters where activities need to be regulated, according to a recent study (UNU, 2005), with no current international bioprospecting or maritime agreements covering the open ocean outside territorial waters.

3.2 Specialized firms engaged in the genomics paradigm

Although the development of new therapeutic compounds is the most attractive use of biodiversity, natural products are potentially important for other industries. The chemical industry is always looking for better catalysts in order to improve its processes and they have also turned to nature looking for the 'perfect' enzyme. New enzymes for textile finishing processes, bleaching paper and food processing could have a major environmental impact by reducing energy and water consumption, reducing the release of toxic substances to the environment (Weintraub, A 2004).

Up until recently, the enormous diversity represented by micro organisms from diverse habitats has not been studied due to the fact that only a few of them can be cultured in laboratory conditions. Today, *metagenomics* allows DNA to be extracted directly from environmental samples to produce libraries containing clones representing the entire

genetic composition of a single habitat. The information held within a metagenomics library can be used to determine community diversity, to identify the presence of specific microorganisms or to identify biosynthesis pathways of interest (Steele and Streit, 2005).

Thanks to metagenomics it has been shown that soil, which was thought to contain a low diversity of micro organisms when analyzed using cultivation based techniques, is one of the most richly diverse habitats for prokaryotic life on Earth. In the same way it has been possible to detect, amplify, clone and screen genes from extreme environments such as geysers, deep seas, salted lakes and deserts. The biologist/entrepreneur Craig Venter has showed that the abyssal zone of the Sargasso Sea is the habitat of hundreds of microbe species never reported before, containing genes that may be the key for the production of a whole new range of substances.

It has been known for some time that marine organisms such as snails, sea squirts and sponges are sources of potentially useful substances. Sponges, for example, are known to be a rich source of bioactive compounds in a variety of pharmacological screens associated with cancer and viral diseases (Haefner, 2003). Metagenomics is being used by an increasing number of small firms to explore the uniquely sophisticated chemical entities of marine organisms and firms as Pharma Mar and Nereus already have several candidates drugs developed from these origins.

4. *Biopiracy* and patenting issues

Research about the properties of plants and other natural resources has being carried out for decades. As mentioned above, biological and genetic resources were considered part of humankind's heritage, given their importance for agriculture and the development of products to improve health. However, after the sovereign rights of states over their resources were adopted by the CBD, it is common to find denouncements of *biopiracy* presenting more or less the same story line: big international firm finds out an interesting compound through the study of traditional practices of peoples living in a tropical forest or any other part of a developing country; the firm steals such *innovation* and makes big profits, without paying compensation either to the country of origin or to the community owning the knowledge.

A closer analysis to such claims seems to indicate that some of the most cited cases of misappropriation of resources and traditional knowledge are at least badly documented, when not purposely manipulated for political ends. Most of the drugs developed on the basis of a resource originated in a developing country happened long before the CBD era, and not all are based in the traditional knowledge of peoples, but in the systematic efforts of researchers of pharmaceutical firms or research institutes. However, the claims of biopiracy targeted at multinational companies and other large organizations have resulted in many bioprospecting projects being halted, since firms do not want to expose themselves to bad press, or to become involved in legal disputes with civil organizations making false claims against them.

After the adoption of the CBD, people opposing bioprospecting frequently appeal to the "unfair" terms of the agreements. Rodriguez (2002) affirms that the agreement between Merck and INBio was badly negotiated and that the Institute gave unprecedented access to Costa Rica's biodiversity for a few dollars. In the same way a judge ordered the renegotiation of a contract signed between Diversa and the National University of Mexico in 1998 after considering it unfair. It is interesting to note that the judge explicitly based his decision upon a publication by ten Kate and Laird (1999) where they recommend that royalties in bioprospecting projects should be fixed between one and five percent.

Scientists have not escaped biopiracy accusations. It has been reported that, as a result of the strict law on access to biodiversity, Brazilian scientists cannot continue their work in areas such as ichthyology and zoology (Astor, 2005). In Mexico, an American scientist who had worked for decades with indigenous communities suffered damage to his reputation when trying to obtain the communities' previous informed consent (PIC) to carry out bioprospecting activities in the framework of the ICBG. It is worth noting that the agreement included clauses to ensure that the communities will receive benefits in the event a product was developed from the resources of the region. In the same way, Craig Venter was awarded the title of The Biopirate of 2006 for collecting marine organisms in the Sargasso Sea and the Mexican Caribbean, in spite of having obtained exploring permits from the Bermudan and the Mexican governments, according to the Convention of the Sea (UN year).

Perhaps the most contentious issue of biopiracy is related to patenting. For the ETC Group (before RAFI) biopiracy is "*the privatization of genetic resources (including those derived from plants, animals, microorganisms and humans) from those people who hold, maintain, embody, develop, breed or otherwise create, foster or nurture those resources*" and "*the biopirates' most frequent modus operandi is intellectual property*". The organization, which claim to have coined the term biopiracy at the beginning of the 1990s, states that "*if a resource is privatized through the patenting system, it is likely that a community that once had access to the resource will no longer have the legal right to use it or may no longer afford to buy it*" (ETC Group, 2004). Shiva (1996) goes beyond this when considering that *patenting biodiversity* is a new form of colonialism exerted by the countries of the North, willing to take possession the strategic resources of the South. In her words "*…through patents and genetic engineering, new colonies are being carved out…*" and that "*…resistance to biopiracy is a resistance to the ultimate colonization of life itself* (pp 5)" [6]

In effect patents are seen as the tool to legalize the misappropriation of resources. After exploring how frequent and damaging the patenting of genetic resources is it is possible to find different situations. Most of the cases of misappropriation correspond to biological resources, i.e. not to the genetic content of the organisms. In a number of cases, patents were granted before the CBD and are not in force any more. In others, the patents have expired by lack of payment and no economic gain was made from them.

[6] Unfortunately Shiva, who enjoys the recognition of different groups of activists –feminists, environmentalists, etc- , does not contribute to the biopiracy issue with more than a stiff discourse reproduced by a lot of NGOs. Along her 150 pages book, she gives one example of *biopiracy* and in spite of alerter about the infamous consequences of patenting practices on communities and knowledge generation, she does not refer a single case.

Some patents have been revoked or are being re-examined after being challenged for not protecting new inventions but rather the traditional use of certain resources. It is worth noting that even when *bad patents* have been granted – the case of the neem tree and the ayahuasca, among others – people have not been prevented of using the resource.[7]

If it is understandable that NGOs, environmentalists and governments over react to the granting of patents over genetic resources with little or no inventive contribution, especially plants and crops, it is more difficult to explain claims of biopiracy when the resource has been only used as a source of information or when is only tangentially related to the invention. Some years ago the Kenyan Wildlife Service (KWS) threatened to launch a claim against Genencor, alleging that the enzymes IndiAge Neutra® and Puradax® were illegally obtained from the Kenyan soda lakes (Barnett, 2004; Sheridan, 2006). Recently the firm arrived at an agreement to compensate the KWS in order to avoid bad press, in spite of accessing the genetic material through a university researcher who collected them before the adoption of the CBD.

However, activists against biopiracy are very careful in not referring to one particular case where the existence of a patent allows the holder to raise profits to share with the local communities. This is the case of the patent obtained by the Council for Science and Industrial Research (CSIR) of South Africa in order to protect the substance known as P57, isolated from the Hoodia tree. The Hoodia, traditionally used by the nomadic Sam tribe in order to avoid hunger and thirst, is currently being commercialized as an anti-

[7] An exception to this is the case of the Mexican yellow bean patented by an American firm which attempted to stop the imports of the crop to the USA. It is worth noting that the patent was not renovated after the complaints of the Mexican firms affected.

obesity product in a market valued at $200 million. Up to the present time the San people have received $1-2 million to improve their living conditions, an important amount for the tribe, if not on a scale to justify global efforts to regulate access to biodiversity.

5. The strategic nature of genetic resources

As part of the research for a PhD that underpins this paper, two interviewees, both scientists and owners of firms acting as intermediaries of biological and genetic resources, pointed out that there is an essential difference between biological and genetic resources. On the one hand biological resources are usually collected and transformed by relatively simple processes and usually their price is fixed in the commodities market. Exceptionally it is possible to find a new functionality associated to such resources, as happened in the case of the Hoodia plant, and then it is possible to claim property rights and to fix a higher value.

On the other hand genetic resources, i.e. the genetic content of an organism, are the materials for scientist to work with, which adds the major part of their value. Their price is difficult to establish through market mechanisms, which partially explains why it is so difficult to calculate a fair compensation for the provider country when carrying out bioprospecting. Genetic resources are utilized in many ways and they are not necessarily present in the final product. Rather, the genetic resource may be a step in a process, a research tool or a catalyst, a fully functional organism or a sub unit of an individual gene.

ten Kate and Laird (2002) carried out a comprehensive study of the sectors intensively using genetic resources for innovation and recognized that the existence of firms such as intermediaries make difficult the implementation of the provisions on ABS of the CBD. Small intermediaries, at the bottom of the value chain, such as small firms and researchers at universities and public research centers with capacities for collecting and extracting samples, can only act as brokers. Larger intermediaries, such as firms with the capacity to prepare samples for the construction of molecular libraries, who operate higher up the value chain, stand to generate far larger revenues, since such libraries may be used for several big firms looking for specific compounds. At the top of the value chain are firms that use proprietary genomic technologies for specific applications in the areas of industrial enzymes, alternative sources of energy, environmental remediation, and therapeutic products can take advantage of the genetic resources of extreme environments and the oceans. Although in theory all the organizations in the value chain are subject to the provisions of the Convention, the ubiquity of their activities make regulation almost impossible.

Genetic resources show characteristics of club goods, i.e. certain agents can benefit from making further investments and adding knowledge to basic principles or products. Big pharmaceutical and chemical firms are typically these agents, since they have the financial capacity to invest in long projects of high risk and have the internal capacities to take advantage of the potential of biodiversity. Even in the case of pharmaceutical firms using ethnobotanical knowledge for research the firm needs to invest and generate

complementary knowledge to transform a 'hit' (bioactive substance) into a marketable product.

Understanding the importance of having more than a passive attitude toward natural resources, some developing countries are investing and generating complementary knowledge to foster the use of their own biodiversity. The regional government of Sarawak, Malaysia, invested in an American firm carrying out research on Calanolide A and B, substances that have shown interesting anti-HIV properties. The regional government owns half of the intellectual property rights and if a successful product is developed will receive half of the profits generated.

In South Africa the Council for Scientific and Industrial Research (CSIR) has established an important bioprospecting program aimed at taking advantage of the 24,000 plant species unique to the country. From late 1998 to 2005, the CSIR has coordinated the collection of about 11,000 plant species, testing around 7,000 extracts for potential anti-cancer drugs in association with the National Cancer Institute (NCI) of the United States. [8]The research capabilities generated through this research have allowed the CSIR's bioprospecting research group to detect 15 potential plant leads for therapeutic areas important for the country such as HIV, malaria, tuberculosis, mosquito repellency, asthma, inflammation and wound-healing.

A counter example that shows that a lot of regulation does not help is the case of the Sorcerer II Expedition leaded by Craig Venter. As mentioned above, Venter carried out bioprospecting activities in Mexican territorial waters, after obtaining the authorization of

[8] CSIR News, http://www.csir.co.za/enews/2008_mar/bio_01.html

the national government. As established in the Convention of the Sea he shared the results of his research with Mexican scientists located at the Ecology Institute of the National University of Mexico in the form of providing a copy of the samples. At Venter's own Institute for Biological Energy Alternatives his team are investigating the possibility of using the metabolic engine of a micro organism for the production of hydrogen. Meanwhile, the samples given to the University have not been yet examined. While regulation has allowed the Mexican state to obtain identical samples to Venter, it has not enabled them to overcome the absence of the organizational capabilities to exploit the potential contained in the samples, despite having adequate resources in personnel and equipment.

6. Conclusions: The challenge of adopting a simple but effective regulation

The implementation of the International Regime on ABS is based upon the assumption that a multilateral approach at the framework of the WTO will give developing countries more power to enforce compliance with the CBD. However, it is not clear whether this effect will be achieved or if, on the contrary, developing countries will lose a degree of liberty to negotiate bioprospecting agreements and take advantage of their genetic resources according to their own biodiversity strategy.

Experts from academia, international institutions and industry seem to agree that no single set of contractual terms can apply to all those concerned with biodiversity, given the variety of firms, and end uses involved (Cragg, 2000; ICC, 2008; ten Kate and Laird, 2002). The international certificate of origin or legal acquisition does not consider such

differences from the point of view of the end users, but attempts to guarantee providers with 'rents' for the simple fact of being biodiverse. However, as seen in section 4.1, bioprospecting is not so lucrative that the cost of major regulations, in financial terms and also in terms of inconvenience, is justifiable. It seems that meeting the costs of compliance is very likely to be a deterrent for firms to carry out bioprospecting.

So far there is little evidence that linking the ABS provisions to the patenting system has been effective in countries where the disclosure of origin has been adopted (Brazil, Costa Rica, the Andean Group and South Africa). Hoare and Tarasofsky (2007) attribute the limited impact of such measures to the fact that the requirements have been in place for an insufficient time, and that they only apply to national patent applications. However, in the PhD research that has led to this paper it has been observed that bioprospecting projects are being shifted from countries where such activities face political opposition and more restrictive regulations towards countries with more flexible frameworks, where they can frequently access the same pool of genetic resources and traditional knowledge.

Given that the adoption of an international regime on ABS is likely to be adopted in the Conference of the Parties in 2010, due to the fact that it has become a political issue, it may be worth considering the establishment of binding and non-binding elements. Officers of patent offices interviewed in the course of the research that led to this paper, as well as representatives of the industry, point out that the disclosure of origin of the genetic resources related to an invention should be considered among the non-binding elements, the absence of which may be taken as an indication of wrongdoing.

Despite this, the main conclusion to be drawn from this paper is not related to identifying the optimum regulatory mechanisms to safeguard biodiversity. Rather, it points to the need for developing countries to acquire capabilities to make use of their resources and reap the benefits of biotechnological innovation in association with the firms engaged in such activities. It would appear that this is the only way for significant benefits to accrue to developing countries from bioprospecting, and the related industrial activities further up the value chain. It is only by understanding, and sharing, the risks involved in this enterprise that the rewards from it can be shared more widely.

Identifying the areas and methods whereby they can actively contribute by adding value to the overall exploitation of biological material, beyond laying claim to the intellectual property alleged to reside within it, is the policy challenge facing governments in developing countries today.

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